

1637  
2024738-7030230000

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Brian Lentricchia, et al.

Serial No.: 10/053,349

Filed: January 15, 2002

For: NUCLEIC ACID EXTRACTION  
SOLUTION AND USE THEREOF

Group Art Unit: Not Yet Assigned

Examiner: Not-Yet-Assigned

RECEIVED

AUG 12 2003

TECH CENTER 1600/2900

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with 37 CFR § 1.97 and 1.98, and, the item identified in this Information Disclosure Statement ("IDS") is brought to the attention of the Office. The item listed on the attached form PTO/SB/08A (08-00) is enclosed.

The item identified in this IDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicant as such.

## CERTIFICATE OF MAILING TRANSMISSION

(37 C.F.R. § 1.8)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposit with the United States Postal Services on the date shown below with sufficient postage as "First Class Mail" to addressee in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

8/15/03  
Date of deposit

Carolyn Tobias

Name of Person transmitting Paper

Carolyn Tobias  
Signature of Person Depositing Paper

**INFORMATION DISCLOSURE STATEMENT FILING PROVISION:**

- ☒ This IDS is believed to be timely in that it is being submitted under 37 CFR § 1.97(b), that is (1) within three months of the filing date of the application, which is not a continued prosecution application filed under § 1.53(d) or (2) within three months of entry of the national stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a first Office action on the merits; or (4) before the mailing of a first Office action after filing a request for continued examination under § 1.114. Thus, no fee is required.
- ☐ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR § 1.17(p) to the deposit account referenced below.
- ☒ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and a statement under 37 CFR § 1.97(e) is included below, thus no fee is required.
- ☐ This IDS is being submitted under 37 CFR § 1.97(c), that is after mailing of a first Office action on the merits, but before a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311.
- ☐ The fee due under 37 CFR § 1.17(p) is submitted herewith.
- ☐ A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this IDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.
- ☐ This IDS is being submitted under 37 CFR § 1.97(d), that is after a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before payment of the issue fee. A statement under 37 CFR § 1.97(e) is included below. The fee due under 37 CFR § 1.17(p) is submitted herewith.

**STATEMENT UNDER 37 CFR § 1.97(e):**

- ☒ Each item contained in this IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS.
- ☐ No item contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this statement after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this IDS.

**PAYMENT AND/OR AUTHORIZATION TO CHARGE FEES:**

- ☐ A check in the amount of \_\_\_\_\_ is enclosed for the above fee(s).  
☐ Please charge \_\_\_\_\_ to Deposit Account No. **50-2518** for the above fee(s).

The Commissioner is authorized to charge any fees required by the filing of these papers, and to credit any overpayment to Bingham McCutchen's Deposit Account No. **50-2518**.

Respectfully submitted,

BINGHAM McCUTCHEN LLP

Dated: 8-5-03

By: DT Burse  
David T. Burse  
Reg. No. 37,104

BINGHAM McCUTCHEN LLP  
Three Embarcadero, Suite 1800  
San Francisco, CA 94111-4067  
(650) 849-4400



# PATENT COOPERATION TREATY

**RECEIVED**

JUN 10 2003

BINGHAM MCCUTCHEEN LLP

From the

**INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY**

To:  
DUNCAN A. GREENHALGH  
TESTA, HURWITZ, & THIBEAULT, LLP  
HIGH STREET TOWER  
125 HIGH STREET  
BOSTON, MA 02110

**PCT**

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference  CYM-036PC		Date of Mailing (day/month/year)  <b>REPLY DUE</b>	within 1 months/days from the above date of mailing  Priority date (day/month/year)  15 January 2001 (15.01.2001)
International application No.  PCT/US02/01430	International filing date (day/month/year)  15 January 2002 (15.01.2002)		
International Patent Classification (IPC) or both national classification and IPC  IPC(7): C12Q 1/68; C07H 19/00 and US Cl.: 435/6; 536/22.1			
Applicant  CYM-036PC			

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2 (a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application
3. The applicant is hereby invited to reply to this opinion.
 

**When?** See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See Rule 66.2(d).~~

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
For an informal communication with the examiner, see Rule 66.6

**If no reply is filed,** the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 15 May 2003 (15.05.2003)

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Jezia Riley <i>Janez Riley</i> Telephone No. 703-308-0196
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Form PCT/YPEA/408 (cover sheet) (July 1998)

*CYM-036*  
*SUPPL. INT. - US*  
**DOCKETED**  
*6-28-03*

*Resp. Writ. Opin.*  
**DOCKETED**  
*6-28-03 FINAN*

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:  
DUNCAN A. GREENHALGH  
TESTA, HURWITZ, & THIBEAULT, LLP  
HIGH STREET TOWER  
125 HIGH STREET  
BOSTON, MA 02110

## PCT

WRITTEN OPINION

(PCT Rule 66)

<p>Applicant's or agent's file reference</p> <p>CYM-036PC</p> <p>International application No.</p> <p>PCT/US02/01430</p> <p>International Patent Classification (IPC) or both national classification and IPC</p> <p>IPC(7): C12Q 1/68; C07H 19/00 and US Cl.: 435/6; 536/22.1</p> <p>Applicant</p> <p>CYM-036PC</p>		<p>Date of Mailing (day/month/year)</p> <p style="font-size: 1.2em;">28 MAY 2003</p> <p>REPLY DUE</p> <p>Within 1 months/days from the above date of mailing</p> <p>15 January 2002 (15.01.2002)</p> <p>15 January 2001 (15.01.2001)</p>
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Name and mailing address of the IPEA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231  
Facsimile No. (703)305-3230

Authorized officer  
Jezia Riley *Janez Riley*  
Telephone No. 703-308-0196

# WRITTEN OPINION

International application No.

PCT/US02/01430

## I. Basis of the opinion

### 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☒ the description:
  - pages 1-22 \_\_\_\_\_, as originally filed
  - pages NONE \_\_\_\_\_, filed with the demand
  - pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the claims:
  - pages 23-26 \_\_\_\_\_, as originally filed
  - pages NONE \_\_\_\_\_, as amended (together with any statement) under Article 19
  - pages NONE \_\_\_\_\_, filed with the demand
  - pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:
  - pages NONE \_\_\_\_\_, as originally filed
  - pages NONE \_\_\_\_\_, filed with the demand
  - pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the sequence listing part of the description:
  - pages 1-3 \_\_\_\_\_, as originally filed
  - pages NONE \_\_\_\_\_, filed with the demand
  - pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE \_\_\_\_\_
- ☐ the claims, Nos. NONE \_\_\_\_\_
- ☐ the drawings, sheets/fig NONE \_\_\_\_\_

### 5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

WRITTEN OPINION

International application No.  
PCT/US02/01430

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 30-35	YES
	Claims 1-29 and 36-40	NO
Inventive Step (IS)	Claims 30-35	YES
	Claims 1-29 and 36-40	NO
Industrial Applicability (IA)	Claims 1-40	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-29 and 36-40 lack novelty under PCT Article 33(2) as being anticipated by Van Ness US 5,124,444.

The reference relates to compositions and assay methods for the extraction and hybridization of nucleic acids. In particular this invention relates to compositions and methods to extract nucleic acids from cells in complex biological samples or specimens. The method is based on the use of the chemical family of compounds termed lactams, preferably pyrrolidones, which promote nucleic acid base pairing and which are effective in the extraction and purification of nucleic acids. The extraction solution will contain standard buffers and detergents to promote lysing of cells. A buffer such as sodium citrate, Tris HCl, PIPES or HEPES, preferably Tris-HCl at a concentration of about 0.05 to 0.1M can be used. The extraction solution will typically also contain about 0.05 to 0.5% of an ionic or nonionic detergent, such as sodium dodecylsulfate (SDS) and between 1 to 10 mM EDTA. To recover total nucleic acid from GnSCN-solubilized bacterial cells, cells were lysed in 100 microliters of 3M GnSCN, 50 mM Tris pH 7.6, 25 mM EDTA and 2% Sarkosyl. 100 microliters of ethylene glycol was then added to the lysate followed by 500 microliters of phenol and 30% microliters of 1% SDS, 50 mM Tris pH 7.6, 25 mM EDTA and 0.05M NaCl.

----- NEW CITATIONS -----  
US 5,124,444 A (VAN NESS et al) 23 June 1992, see entire document.

WRITTEN OPINION

International application No.  
PCT/US02/01430

**Supplemental Box**  
(To be used when the space in any of the preceding boxes is not sufficient)

**TIME LIMIT:**

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.